UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

THOMAS A. SIMONIAN,)	
Plaintiff,)	
v.)	Civil Action No. 1:10-cv-01539
ASTELLAS PHARMA US, INC.,)	Honorable Charles R. Norgle, Sr.
Defendant.)	
)	
)	

<u>DEFENDANT'S MEMORANDUM OF LAW IN SUPPORT OF</u> <u>ITS MOTION TO DISMISS PURSUANT TO RULE 9(B) AND 12(B)(6)</u>

Defendant Astellas Pharma US, Inc. ("Astellas"), by and through its undersigned attorneys, respectfully requests the Court grant its Motion to Dismiss pursuant to Fed. R. Civ. P. 9(b) and 12(b)(6) for Thomas A. Simonian's ("Simonian") failure to plead with particularity his claims for false marking under the False Marking Statute, 35 U.S.C. § 292.

I. INTRODUCTION

Simonian alleges that Astellas violated the False Marking Statute, 35 U.S.C. § 292, which imposes civil penalties for purposefully deceitful acts of marking "unpatented" articles with the numbers of United States patents. (*See* Compl.) Specifically, Simonian alleges that Astellas falsely marked the package insert of its AMEVIVE® prescription pharmaceutical product with an expired patent number. (*See id.*) Simonian alleges that Astellas continued marking its package

¹ Astellas notes that Simonian identifies United States Patent No. 4,956,281 in the Complaint as the expired patent number marked on Astellas's product, but attaches a different patent as Exhibit B to the Complaint and discusses that other patent in paragraphs 20 and 21. For purposes of this motion, Astellas assumes Simonian intended to attach and discuss United States Patent Number 4,956,281.

insert with the patent number, despite the expiration of the patent. Simonian concludes, "upon information and belief," that Astellas falsely marked the product packaging "for the purpose of deceiving the public into believing that something contained in or embodied in the product is covered by or protected by the expired '281 patent." (*Id.* ¶ 27.)

Simonian's false marking allegations are based on claims of fraud, and therefore are subject to heightened pleading requirements of Fed. R. Civ. P. 9(b), as other district courts have recognized. Simonian's complaint does not withstand Rule 9(b) scrutiny.

II. ARGUMENT

"The false marking statute [*i.e.*, 35 U.S.C. § 292] is a fraud-based claim, which is subject to the pleading requirements of [Rule] 9(b)." *Juniper Networks v. Shipley*, No. C 09-696 SBA, 2009 WL 1381873, at *4 (N.D. Cal. May 14, 2009); *see also Inventorprise, Inc. v. Target Corp.*, No. 09-CV-00380, 2009 WL 3644076, at *7 n. 16 (N.D.N.Y. Nov. 2, 2009), *United States ex rel. Scharmer v. Carrollton Mfg. Co.*, 377 F. Supp. 218, 221 (N.D. Ohio 1974) (summarizing false marking claim as a "contention . . . [of] a conscious fraud.").

Rule 9(b) requires that "[i]n *all* averments of fraud ... the circumstances constituting fraud ... *shall* be stated with particularity." Fed. R. Civ. P. 9(b) (emphases supplied). Rule 9(b) requires that a plaintiff set forth the activities underlying alleged frauds, the identity of those involved, and their dates, times, and places. *See Borsellino v. Goldman Sachs Group, Inc.*, 477 F.3d 502, 509 (7th Cir. 2007) (citing *Heffernan v. Bass*, 467 F.3d 596, 601 (7th Cir. 2006)); *see also Windy City Metal Fabricators & Supply, Inc. v. CIT Tech. Fin. Servs. Inc.*, 536 F.3d 663, 668 (7th Cir. 2008); *Bankers Trust Co. v. Old Republic Ins. Co.*, 959 F.2d 677, 683 (7th Cir. 1992). Essentially, allegations must state "the who, what, when, where, and how" of the misconduct charged. *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990); *see also*

United States ex. rel. Gross v. AIDS Research Alliance-Chicago, 415 F.3d 601, 605 (7th Cir. 2005).

Rule 9(b) serves several important purposes, including ensuring the defendant:

is given adequate notice of the specific activity that the plaintiff claims constituted the fraud so that the accused party may file an effective responsive pleading. Courts have a special institutional interest in seeing that such allegations are made with care so that claims advanced solely for their nuisance or settlement value can be quickly identified and valuable public judicial resources are not wasted.

Lachmund v. ADM Investor Servs., Inc, 191 F.3d 777, 783 (7th Cir. 1999).² A dismissal for failure to comply with Rule 9(b) is a dismissal on the pleadings for failure to state a claim. Fed. R. Civ. P. 9(b), 12(b)(6); Gross, 415 F.3d at 605. Simonian's complaint should be dismissed for failure to meet the heightened pleading standards of Rule 9(b) because Simonian fails to allege Astellas's fraudulent *intent* with particularity.

Rule 9(b) requires Simonian to plead facts sufficient to support his allegations of fraudulent *intent*, *i.e.*, that Astellas acted "for the purpose of deceiving the public." 35 U.S.C. § 292(a). Simonian fails to do so.

² It is for these same reasons that courts require inequitable conduct claims (which, like false marking claims, sound in fraud) to be pled under Rule 9(b). *Exergen Corp. v. Wal-Mart Stores*, 575 F.3d 1312, 1326-27 (Fed. Cir. 2009); *Juniper Networks*, 2009 WL 1381873, at *4 (relying on precedent which held that Rule 9(b) applies to inequitable conduct claims, in holding that Rule 9(b) applies to false marking claims). And the purposes served by Rule 9(b) accord with the Supreme Court's recent precedent regarding the default standards of pleading under Rule 8. *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) ("A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do' ... Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.' ... Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief."") (citing to *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-557 (2007)).

Simonian's conclusory assertions that Astellas is a "sophisticated company" that "knows, or should know" that products were marked with expired patent numbers fail to pass muster under Rule 9(b). *See Juniper Networks*, 2009 WL 1381873 at *4 (conclusory allegations that defendant "knew" marked product not covered by patent were insufficient under Rule 9(b)). In *Juniper Networks*, the court rejected a similarly-styled pleading that alleged the defendant marked an article "kn[owing] that language to be false" *Id.* The court noted that false marking claims under 35 U.S.C. § 292 are subject to Rule 9(b) standards, and that the conclusory allegations "that [defendant] 'knew' his reference to the patents was 'false' are . . . insufficient to plead an intent to deceive under section 292(a)." *Id.*

Like the relator in *Juniper Networks*, Simonian's intent pleadings are bare of any factual support and are insufficient under Rule 9(b). Simonian's allegations that expired patent numbers appear on a product are meaningless with respect to any intent associated with the act of marking. At most, Simonian's complaint amounts to allegations of suspicious circumstances that are insufficient to satisfy his obligation to plead fraudulent intent with particularity. Simonian's complaint lacks any facts to support a conclusion that the products in question were marked with any intent, much less "for the purpose of deceiving the public" under 35 U.S.C. § 292(a).

Indeed, in a very recent decision in the U.S. District Court for the District of Delaware, the Court dismissed similarly threadbare pleadings of intent as insufficient to meet even the default pleading standards of Rule 8(a), *Iqbal*, and *Twombly*. *Brinkmeier v. Graco Children's Prods. Inc.*, No. 09-262-JJF, 2010 WL 545896 (D. Del. Feb. 16, 2010). Like Simonian does here, the *Brinkmeier* relator tried to parlay the appearance of the numbers of expired patents on products in the stream of commerce into an inference of deceptive intent. *See id.* at *4-5. In particular, the *Brinkmeier* relator alleged: (1) that defendant had an Intellectual Property

Manager responsible for patent markings; (2) that because certain patents had expired, defendant "cannot have any reasonable belief that such products are protected by such patents"; (3) that defendant "knows, or should know" that the products have been falsely marked; and (4) that "[u]pon information and belief, [defendant] marked products . . . with expired patents for the purpose of deceiving the public into believing that something contained in or embodied in the products is covered by or protected by the expired patent[s]." *Id.* The *Brinkmeier* court rejected these pleadings under default Rule 8(a) standards: "These allegations alone do not supply enough factual matter to suggest an intent to deceive, and amount to nothing more than the 'mere labels and conclusions' prohibited by *Twombley* [sic]." *Id.*³ Given that Simonian's pleadings are similarly conclusory, they also fail to satisfy the default standards of Rule 8(a), let alone the heightened standards of Rule 9(b).

III. CONCLUSION

For all the reasons stated above, the Court should dismiss Simonian's complaint under Rule 12(b)(6) for failure to plead false marking with particularity under Rule 9(b).

³ In *Brinkmeier*, the court also found that the relator pled sufficient facts as to <u>one</u> patent marking because it alleged that (1) defendant had been sued by two competitors for infringing the marked patent and (2) defendant revised its patent marking at least three times since the marked patent expired in June 2007. *Id.* at *4. Simonian's pleadings come nowhere close to that level of detail.

WHEREFORE, Astellas respectfully requests that the Court enter an order: (1) granting this Motion to Dismiss in its entirety; and (2) granting any such further relief as the Court deems appropriate and just.

Dated: May 10, 2010 Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Jaclyne D. Wallace, an attorney, certify that I electronically filed the foregoing with the

Clerk of Court of the CM/ECF system on May 10, 2010, which will send notification and service

of such filing to all counsel of record.

/s/ Jaclyne D. Wallace

Jaclyne D. Wallace